

Message Text

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21

ORIGIN HEW-06

INFO OCT-01 ISO-00 OES-05 EUR-12 AF-06 MED-03 /033 R

DRAFTED BY DHEW/FDA/JRWEINROTH; M.D.

APPROVED BY OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

EUR/WE:KSHIRLEY (INFO)

AF/S:RJDOLS (INFO)

----- 037881

R 241527Z APR 75

FM SECSTATE WASHDC

TO AMEMBASSY BRUSSELS

AMEMBASSY PRETORIA

UNCLAS STATE 094433

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, BE, SF.

SUBJECT: FDA ADVISORY-SUBPOTENT DIAGNOSTIC PRODUCT

1. FDA ADVISES THAT THE HEPATITIS B SURFACE ANTIGEN (HUMAN) (SUBTYPE A Y W) COATED HUMAN RED BLOOD CELLS LABELED "FOR USE IN PHA TESTS, CAUTION: MAY TRANSMIT HEPATITIS." MANUFACTURED BY ELECTRO-NUCLEONICS LABORATORIES, INC., BETHESDA, MARYLAND 20014 IN THREE ML. AND 25 ML. VIALS IS SUBPOTENT. THE LOT NO. OF THE A Y W CELLS INVOLVED IS 002. THIS LOT NUMBER IS STAMPED ON VIALS WITH LIST NO. 2052 (3 ML.) AND LIST NO. 2053 (25 ML.) WHICH WERE PACKAGED IN VIRGO REAGENTS TEST KIT NO. 2000, LOT NO. 1073.

2. VIRGO REAGENTS TEST KIT NO. 2000, HEPATITIS B SURFACE ANTIGEN (HUMAN) COATED HUMAN RED BLOOD CELLS, IS USED IN A PASSIVE HEMAGGLUTINATION TEST FOR THE DETECTION OF ANTIBODY TO THE HEPATITIS B SURFACE ANTIGEN. THE "DIRECTIONS FOR USE" FOR THIS TEST KIT ARE GIVEN ON THE PRODUCT INSERT. IN GENERAL, THE TEST IS POSITIVE WHEN THE HEPATITIS ANTIGEN (LIST NO. 2052 OR NO. 2053) COMBINES WITH A PATIENT'S BLOOD SAMPLE (ANTIBODY) TO FORM AN AGGUTINATION. AT THE SAME TIME, A CONTROL IS RUN USING A STANDARDIZED ANTIBODY (LIST NO. 6048) USING VARIOUS DILUTIONS. WHEN A POSITIVE TEST RESULT IS OBTAINED FROM AN ANTIBODY DILUTION GREATER THAN UNCLASSIFIED

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1 TO 28, THE TEST IS DEEMED FAULTY. IT WOULD INDICATE THAT THE

STABILITY OF THE HEPATITIS ANTIGEN HAS DETERIORATED. THIS IS THE
CASE WITH LOT NO. 002 OF HEPATITIS B SURFACE ANTIGEN (HUMAN)
7?5603 A Y W) COATED HUMAN RED BLOOD CELLS.

3. POSTS ARE REQUESTED TO DETERMINE IF THE FOREIGN CONSIGNEES
HAVE RECEIVED ADVISORY FROM FIRM INDICATING POSSIBLE PROBLEM
WITH DIAGNOSTIC PRODUCT.

4. FOREIGN CONSIGNEES AS FOLLOWS:
UNIVERSITY CATHOLIQUE CLINIQUES UNIVERSITAIRES SAINT-PIERRE,
BRUSSELESTRAAT 69, B-3000 LEUVEN, BELGIUM
T AND C SCIENTIFIC SUPPLIES, P.O. BOX 1366 JOHANNESBURG, SOUTH
AFRICA END
KISSINGER

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NNN

Message Attributes

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Capture Date: 01 JAN 1994
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Margaret P. Grafeld
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To: BRUSSELS PRETORIA
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